

REMARKS

Claims 1, 2, and 4-31 are pending. Claims 32-49 have been withdrawn. Claims 20 and 21 have been amended to provide clarity in the dependencies. Support for the amendment is found throughout the specification, for example at original [0029].

Rejections under 35 U.S.C. § 112

On page 2 of the Final Office Action, the Examiner rejects claims 1, 2, and 4-31 under 35 U.S.C. § 112, second paragraph, “as being indefinite.” Applicants traverse the rejection.

The Examiner asserts that the claims are confusing as to how a fabric can be prepared containing only one yarn, and how one yarn can contain only one fiber. The Examiner’s assertions regarding conventional or normal definitions are appreciated but do not apply to the instant claims. A fundamental principle of patent law is that the inventor may define the terms of his invention. *See, e.g., CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (“[A] claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in . . . the specification . . . ”); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”). Moreover, claims need only “reasonably apprise those skilled in the art” of their scope. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986).

In the instant application, the Applicants have defined the meaning of “a yarn” to include one fiber, and have shown a fabric that is made from one fiber. Referring to the published version of the instant application, Pub No. 20040224406, the specification teaches, for example, that:

[0088] **Fabrics** can also be formed from similar constructs of purified **filaments**, and used in various applications. Fabrics can be divided into various classes, including woven, non-woven, knitted fabrics, and stitch-bonded fabrics, each with numerous subtypes. Each of these types may be useful as an implant in particular circumstances. In discussing these silk-based fabrics, we describe the natural silk, e.g., of *Bombyx mori*, as a “fibroin fiber.” The fibers should be at least one meter long, and this length should be maintained throughout the process to facilitate their handling during processing and incorporation into a fabric. Given that a yarn may be defined as an assembly of fibers twisted or otherwise held together in a continuous strand and that a **single fibroin fiber**, as defined above, is comprised of multiple plied broins, sometimes from multiple cocoons, **a single fibroin fiber may be termed a**

“yarn.” As well, fibroin fibers are twisted together or otherwise intertwined to form a “yarn.”

[0097] Wet laydown was selected for a prototype of ***fabric*** formation because it is the simplest procedure. The ***non-woven product*** (FIG. 20A) was *created from a single silk fibroin fiber* prior to extraction at the fabric level. (Emphasis added; *see also* [0106])

Hence, one of ordinary skill in the art would be reasonably apprised, upon reading the specification, that the term “yarn” also refers to one fiber, and that the “fabric” also refers to a fabric made of one fiber. Under the correct legal standard, the claims are not indefinite, and the rejection should be withdrawn.

Rejections under 35 U.S.C. § 103

On page 3 of the Final Office Action, the Examiner rejects claims 1, 2, and 4-31 under 35 U.S.C. § 103 “as being unpatentable over Armato et al (7,285,637), and if necessary in view of Li et al (6,303,136) and Takewaza et al (5,736,399).” Applicants traverse the rejection.

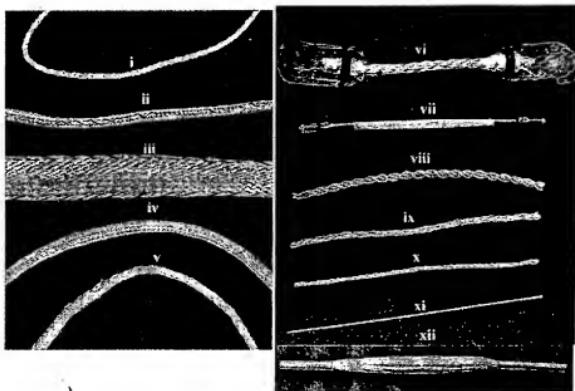
In the Final Office Action, the Examiner found the 37 C.F.R. §1.131 Declaration of Gregory H. Altman, Ph.D. (“Altman Declaration”) defective because it was not signed by all the co-inventors. The undersigned apologizes for this oversight, and provides a Declaration signed by all inventors. Further regarding the Declaration, the Examiner states, on page 4, that the exhibits submitted with the Declaration “do not describe an invention as presently claimed, i.e., a fabric comprising one or more yarns comprising on or more sericin-extracted fibers. The exhibits do not mention fabric and yarn. Exhibit B only discloses removing sericin from silk fibers.” This is not correct.

The exhibits do, in fact, address the pending claims. For example, Applicants have already demonstrated that silk fibers are included in the definition of yarn. Further, on the first page of Exhibit B, the Examiner’s attention is invited to the fourth full paragraph, describing a “six-cord construct” in which fibers are bundled and twisted into “strands” and then twisted into “cords” which are arranged in parallel to form a prosthetic ACL. Although the text does not use the word “yarn,” it is clear from the instant application (*see, e.g.*, [0088] above), that the fibers, twisted strands, and cords of Exhibit B, fall within the “yarn” of the instant claim. Moreover, the instant specification makes it clear that “fabrics” also includes organized yarns:

[0031] Of note, *the textile methods of braiding, in addition to making yarns, can also be used to make fabrics, such as a flat braided fabric or a larger circular braid (FIG. 4A)*. Inversely, weaving and knitting, two fabric forming methods, although not commonly used, can also be used to make yarns. In such instances, *the differentiation between a "yarn" and a "fabric" is not entirely apparent*, and the homogeneity should be used to make clear distinctions, i.e., a yarn is typically more homogeneous in composition and structure than a fabric.

[0036] In other aspects, silkworm fibroin fibers, in the form of a yarn or of a larger construct of yarns, now termed a device, is stripped of sericin, and made (e.g., woven, knitted, non-woven wet laid, *braided*, stitch bonded, etc.) *into a fabric*, sterilized and used as an implantable supporting or repair material that offers a controllable lifetime (i.e., degradation rate) and a controllable degree of collagen and/or extracellular matrix deposition. (Emphasis added.)

With reference to Figure 4A, this shows a variety of what are considered "fabrics" according to the claimed invention:



Thus, the prosthetic ACL six-cord structure described in Exhibit B clearly falls within the demonstrated definition of a "fabric" of the instant claims. Similarly, the silk matrix of fibers organized into a wire rope design of Exhibit A clearly falls within the definition of "yarn" and "fabric" of the claimed invention. The Inventors have testified that although the Exhibits do not use

the term “fabric” or “yarn”, the several of the silk fiber structures in the Exhibits are a “yarn” or “fabric” of the claimed invention.

The Examiner also alleges that the Declaration is defective in not stating that the claimed invention was made in this country. The Examiner’s attention is invited to ¶ 3 of the Declaration dated August 4, 2008, wherein it recites, “Prior to September 28, 2001 we had conceived and reduced to practice, in the United States, the invention as claimed ...” This language is present in the instant Declaration as well.

Hence, the Declaration and Exhibits demonstrate that the Inventors had conceived of the claimed invention in the U.S. prior to September 28, 2001. Therefore, Armato no longer qualifies as a § 103 reference, and the rejection should be withdrawn.

Regarding Li, as Dr. Kaplan stated in his Declaration of Oct. 29, 2007, of record and incorporated herein by reference, Li refers to non-degradable silk suture matrix surrounded by a semi-permeable membrane. By contrast, the fibers of the claimed invention are inherently degradable and unsuitable for the device of Li. Hence, there is no suggestion to make this substitution or a reasonable expectation of success that this could be achieved.

Regarding Takewaza, Dr. Kaplan explained in his Declaration how this reference teaches away from the claimed invention because it requires non-degradable threads. The fibers of the instant claims are degradable, and thus would not serve in Takewaza’s culture carrier in which cells proliferate three-dimensionally.”

Therefore, there is no reason to combine Li and Takewaza because both references require non-degradable threads. As such, the combination of Li and Takewaza fail to support a § 103 rejection, and the rejection should be withdrawn.

Double Patenting

On page 5 of the Final Office Action, the Examiner provisionally rejects claims 1, 2, and 4-31 “on the ground of obviousness-type double patenting” over “claims 1-19 of U.S. Patent No. 6,902,932 B2 in view of Armato et al.” Applicants traverse this rejection. Armato is no longer available to support a § 103 rejection. Nevertheless, in an effort to expedite prosecution, a terminal disclaimer is filed herewith.

CONCLUSION

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. The Commissioner is hereby authorized to charge any payment deficiency to Deposit Account No. 50-0850. Any overpayments should also be deposited to said account. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicants' representative designated below.

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Respectfully submitted,

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